

K111204

**510(k) Summary of Safety and Effectiveness**

DEC 22 2011

**510(k) Submitter:** Streck  
7002 South 109<sup>th</sup> Street  
Omaha, NE 68128

**Official Correspondent:** Bert Moses, Director of Quality  
(402) 537-5343

**Date Prepared:** April 12, 2011

**Name of Device:**

Trade Name: CELL-DYN 22 Plus Calibrator  
Common Name: Assayed Hematology Calibrator  
Classification Name: Calibrator for Cell Indices (864.8150)

**Predicate Device:** Cal-Chex (K840261) Manufactured by Streck

**Description:**

CELL-DYN 22 Plus Calibrator is an in-vitro diagnostic product that may contain any or all of the following: stabilized human or mammalian red blood cells, human, mammalian or simulated white blood cells and a platelet component in a preservative medium. The product is packaged in polypropylene plastic vials containing 2.5ml. The closures are polypropylene screw caps with polyethylene liners. The vials will be packaged in a four (4) welled vacuum formed clamshell container with the package insert / assay sheet. The product must be stored at 2 - 10° C.

**Intended Use:**

CELL-DYN 22 Plus Calibrator is manufactured for calibration of the CELL-DYN Emerald 22 system.

Assayed parameters include: WBC ( $10^9/L$ ), RBC ( $10^{12}/L$ ), HGB (g/dL), MCV (fL), PLT ( $10^9/L$ )

**Comparison to Predicate Device:**

	<b>Cal-Chex (Predicate Product)</b>	<b>CELL-DYN 22 Plus Calibrator</b>
<b>Intended Use Statement</b>	Cal-Chex is used to calibrate multi-parameter hematology analyzer.	CELL-DYN 22 Plus Calibrator is manufactured for calibration of the CELL-DYN Emerald 22 system.  Assayed parameters include: WBC ( $10^9/L$ ), RBC ( $10^{12}/L$ ), HGB (g/dL), MCV (fL), PLT ( $10^9/L$ )
<b>Open Vial Stability</b>	5 days	Same
<b>Closed Vial Stability</b>	45 days	Same
<b>Reagents</b>	The whole blood reagent may contain any or all of the following: stabilized human or mammalian red blood cells, human, mammalian or simulated white blood cells and a platelet component in a preservative medium.	Same
<b>Storage Conditions</b>	2 - 10°C	Same

**Discussion of Tests and Test Results:**

Five types of studies were conducted to establish performance of CELL-DYN 22 Plus Calibrator. The five tests conducted were Run-to-Run Reproducibility, Closed-Vial Stability, Open-Vial Stability, Calibrator Performance Verification and Calibration Equivalency. All testing showed that CELL-DYN 22 Plus Control is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

**Conclusions Drawn From Tests:**

Study results show CELL-DYN 22 Plus Calibrator to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating. CELL-DYN 22 Plus Calibrator is a safe and effective product, which fulfills its intended use when used as instructed in the product information sheet.



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Streck Inc.  
c/o Ms. Deborah S. Kipp  
Quality Assurance Coordinator  
7002 South 109th Street  
Omaha, NE 68128

DEC 22 2011

Re: k111204  
Trade/Device Name: CELL-DYN 22 Plus Calibrator  
Regulation Number: 21 CFR 864.8150  
Regulation Name: Calibrator for cell indices  
Regulatory Class: Class II  
Product Code: KRX  
Dated: December 21, 2011  
Received: December 22, 2011

Dear Ms. Kipp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

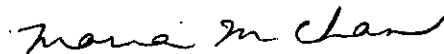
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will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.

Director

Division of Immunology and Hematology Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

### Indication for Use Form

510(k) Number (if known): K111204

Device Name: CELL-DYN 22 Plus Calibrator

Indications For Use:

CELL-DYN 22 Plus Calibrator is manufactured for calibration of the CELL-DYN Emerald 22 system.

Assayed parameters include:

WBC ( $10^9/L$ ), RBC ( $10^{12}/L$ ), HGB (g/dL), MCV (fL), PLT ( $10^9/L$ )

Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria M. Chen  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K111204